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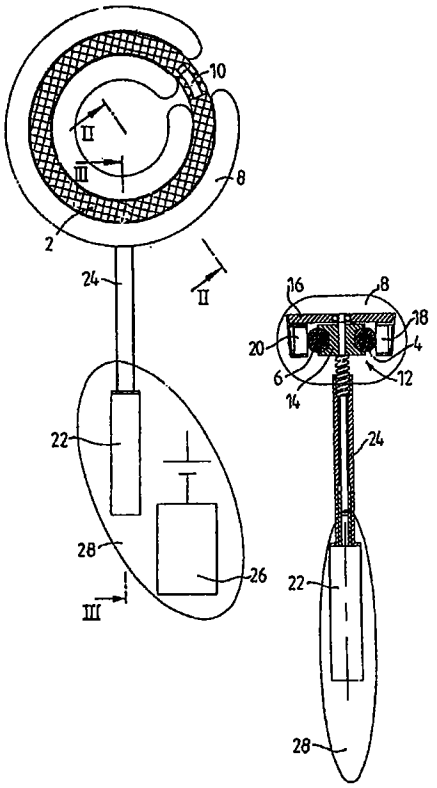
(57) Abstract

A device for forming a stoma opening in the stomach or esophagus of a patient comprises an elongated restriction member (2), forming means (10) for forming the elongated restriction member into at least a substantially closed loop around the stomach or esophagus, said loop defining a restriction opening (3), and an adjustment means (12) for adjusting the restriction member in said loop to change the size of said restriction opening. The adjustment means (12) is designed to mechanically adjust the restriction member in a non-invasive manner to allow post-operation non-invasive adjustments of the restriction member.



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Food intake restriction device

The present invention relates to a food intake restriction device for forming a stoma opening in the stomach or esophagus of a patient, the device comprising an elongated restriction member, forming means for forming the elongated restriction member into at least a substantially closed loop around the stomach or esophagus, said loop defining a restriction opening, and an adjustment means for adjusting the restriction member in said loop to change the size of said restriction opening. The term "patient" includes an animal or a human being.

Food intake restriction devices in the form of gastric banding devices, in which a band encircles a portion of a patient's stomach to restrict the food intake of the patient, have been used in surgery for morbid obesity to form a small gastric pouch above the band and a reduced stoma opening in the stomach. Although such a band is applied around the stomach to obtain an optimal stoma opening during surgery, some prior gastric banding devices are provided with an adjustment means enabling a minor post-operation adjustment of the size of the stoma opening. In all such prior art devices such as disclosed in U.S. Patent No. 4,592,339, European Patent No. 0611561 and International Patent Application WO 94/27504, the adjustment means typically comprises an inflatable cavity in the band and an injection port in fluid connection with the inflatable cavity. The injection port is subcutaneously implanted to allow the addition of fluid to or withdrawal of fluid from the cavity by an injection needle penetrating the patient's skin into the injection port. In practice, the band is made of silicone rubber which is a material approved for implantation and the fluid is a liquid such as an isotonic salt solution.

It has been found, however, that the bands of this type of prior art devices used for forming a stoma opening in a patient's stomach may eventually dislocate downwardly on the stomach and there is an increased risk of stoma stenosis due to a small range of adjustment of the band. It has also been found that the volume of the gastric pouch above the band increases in size up to ten times after operation. Therefore the pouch

volume during surgery needs to be very small, approximately 7 ml. To enable the patient to feed the stomach with sufficient nutrition immediately after an operation considering such a small gastric pouch, the stoma initially needs to be relatively large and later needs to be substantially reduced, as the pouch volume increases. To be able to achieve a significant range of adjustment of the band, the cavity in the band has to be relatively large and is defined by a thin flexible wall, normally made of silicone material. Furthermore, the size of the stoma opening has to be gradually reduced during the first year after surgery as the gastric pouch increases in size. As indicated above, the reduction of the stoma opening using the prior art devices is achieved by adding liquid to the cavity of the band via the injection port to expand the band radially inwardly.

A great disadvantage of repeatedly injecting liquid via the injection port is the increased risk of the patient getting an infection in the body area surrounding the injection port. If such an infection occurs the injection port has to be surgically removed from the patient. Moreover, such an infection might be spread along the tube interconnecting the injection port and the band to the stomach, causing even more serious complications. Thus, the stomach might be infected where it is in contact with the band, which might result in the band migrating through the wall of the stomach. Also, it is uncomfortable for the patient when the necessary, often many, post-operation adjustments of the stoma opening are carried out using an injection needle penetrating the skin of the patient into the injection port.

It may happen that the patient swallows pieces of food too large to pass through the restricted stoma opening. If that occurs the patient has to visit a doctor who can remove the food pieces, if the band design so permits, by withdrawing some liquid from the band to enlarge the stoma opening to allow the food pieces to pass the stoma. Then, the doctor has to add liquid to the band in order to regain the restricted stoma opening. Again, these measures require the use of an injection needle penetrating the skin of the patient, which is

uncomfortable for the patient.

Another problem with known adjustable gastric banding devices is that isotonic salt solution can diffuse from the inflatatle cavity of the band through the surrounding band walls of silicone rubber when there is a slight overpressure prevailing in the cavity. There is also a risk some time after the operation of liquid leakage from the injection port, from the tube between the latter and the band, and from the band itself. Most critical is the inflatable balloon cavity.

An object of the present invention is to provide a food intake restriction device in which the risk of liquid leaking from the device within the patient's body is substantially reduced or eliminated.

Another object of the invention is to provide a food intake restriction device which does not require the use of an injection needle for accomplishing post-operation adjustments of the stoma opening.

Yet another object of the invention is to provide a food intake restriction device which permits post-operation adjustments that are comfortable for the patient.

These objects are obtained by a food intake restriction device of the kind stated initially, which is characterised in that the adjustment means is designed to mechanically adjust the restriction member in a non-invasive manner to allow post-operation non-invasive adjustments of the restriction member. As a result, there is no liquid directly involved in the elongated restriction member itself for providing inflation thereof, enabling post-operation adjustments of the device of the invention to change the stoma opening of the patient. The adjustment means may be incorporated in the restriction member as well as being controlled by hydraulic means. The expression "post-operation non-invasive adjustment means" means that the adjustment means is capable of adjusting the restriction member after the operation without the need for invasive measures, such as penetration of the skin for example by injection needles or surgery, or by any other means that penetrate the skin. Though an injection port could be used in embodiments using hydraulic means, the port preferably would be for

enabling a single, once and for all, calibration of the amount of liquid contained by the hydraulic means.

In accordance with a preferred first adjustment principle, the adjustment means is adapted to adjust the longitudinal extension of the elongated restriction member in a loop form.

In a preferred embodiment of the invention utilizing the first adjustment principle, the restriction member comprises a main portion and two elongated end portions, and the adjustment means is adapted to establish longitudinal relative displacement between the end portions of the restriction member, so that the size of the restriction opening is adjusted. The forming means may comprise any suitable known or conventional device capable of practicing the desired function, such as a spring material forming the elongated restriction member into the loop, so that the restriction opening has a predetermined size, and the adjustment means may be adapted to adjust the restriction member against the spring action of the spring material. In other words, the restriction member may comprise a spring clip. The spring material may be integrated in the restriction member.

Preferably, the adjustment means comprises a movement transferring member, suitably a drive wheel, in engagement with at least one of the end portions of the restriction member and operable to displace said one end portion relative to the other end portion of the restriction member. The drive wheel may advantageously be in engagement with both of the end portions of the restriction member and be operable to displace said end portions relative to each other. An elongated flexible drive shaft may be operatively connected to the drive wheel, for transferring manual or motor generated power from a location remote from the restriction member. In its simplest embodiment, the drive wheel may comprise a pulley in frictional engagement with the restriction member. As an alternative, a gear rack may be formed on at least one of the end portions of the restriction member and the drive wheel may comprise a gear wheel in mesh with the gear rack. Other suitable known or conventional mechanisms may also or alternatively be used as the adjustment means.

The movement transferring member may alternatively comprise at least one cylinder and a piston, which is movable therein and is connected to one of the end portions of the restriction member, the piston being operable to longitudinally displace said one end portion of the restriction member relative to the other end portion of the restriction member. Alternatively, the movement transferring means may comprise two interconnected cylinders and two pistons in the respective cylinders connected to said end portions, respectively, of the restriction member, the pistons being operable to longitudinally displace the end portions of the restriction member relative to each other. Other known or conventional devices also or alternatively can be used as the movement transferring member.

A motor, which is fixed relative to the main portion of the restriction member and has a rotating drive shaft operatively connected to the movement transferring member, may be positioned relative to the elongated restriction member such that the drive shaft extends transverse thereto. Alternatively, the motor may be positioned relative to the elongated restriction member such that the drive shaft extends substantially tangentially to the loop of the restriction member.

In another embodiment of the invention utilizing the first adjustment principle, the elongated restriction member is longitudinally resilient and the adjustment means comprises a contracting means adapted to longitudinally contract the resilient restriction member. Preferably, the elongated restriction member comprises a substantially nonresilient main portion and an end portion forming an elongated helical spring, which is contractable by the contracting means. The contracting means may suitably comprise an elongated flexible pulling member connected to the main portion of the restriction member and extending through the helical spring to contract the helical spring against an arresting member, which is fixed relative to the main portion of the restriction member. The pulling member may extend in an elongated tube joined at one end thereof to the arresting member, so that a motor remote

from the restriction member may be attached to the other end of the elongated tube and pulls the pulling member through the tube to contract the helical spring.

In yet another embodiment of the invention utilizing the first adjustment principle, the elongated restriction member comprises an elongated helical spring having a free end, and a body to which the spring is nonrotatably secured at its opposite end. The adjustment means is adapted to rotate the helical spring in one direction to enlarge the coils of the helical spring to longitudinally contract the spring and to rotate the spring in the opposite direction to reduce the size of the coils of the spring to longitudinally extend spring. As a preferred alternative, the restriction member comprises a further elongated helical spring having a free end and nonrotatably secured to the body at its opposite end, and the adjustment means comprises a drive shaft having two opposite end portions connected to the springs, respectively, at their free ends, the helical coils forming left and right hand helices, respectively. The adjustment means may alternatively comprise gearing having an input shaft and two opposite aligned output shafts connected to the helical springs, respectively, at their free ends, the input shaft being connected to said output shafts so that the output shafts rotate in the opposite directions upon rotation of the input shaft, the helical coils forming the same helices.

In accordance with a second adjustment principle, the adjustment means is adapted to mechanically adjust the restriction member so that at least a portion of a radially innermost circumferential confinement surface formed by the restriction member in the loop of the restriction member is substantially radially displaced in the loop.

In one embodiment of the invention utilizing said second adjustment principle, the restriction member comprises an elongated voltage responsive element forming part of the confinement surface and capable of bending into a bow in response to a voltage applied across the element, the radius of curvature of the bow being adjustable by changing the level of the voltage.

In another embodiment of the invention utilizing said second adjustment principle, the adjustment means is adapted to change the diameter of an elastic annular element of the restriction member, which forms the confinement surface. Preferably, the forming means comprises a substantially rigid outer annular element coaxially surrounding the elastic annular element, and the adjustment means comprises means for pulling the elastic annular element radially outwardly towards the outer annular element to expand the elastic annular element. For example, the pulling means may comprise a plurality of threads secured to the elastic annular element along the circumference thereof and running from the elastic annular element via guide members attached to the outer annular element.

In yet another embodiment of the invention utilizing said second adjustment principle, the forming means comprises a substantially rigid outer annular element, and the restriction member comprises an elongated helical spring extending internally along the outer annular element and contacting the latter. The helical spring forms part of the circumferential confinement surface and has a free end. The restriction member further comprises a body to which the spring is nonrotatably secured at its opposite end. The adjustment means is adapted to rotate the helical spring in one direction to enlarge the coils of the spring to contract the circumferential confinement surface and to rotate the spring in the opposite direction to reduce the size of the coils of the spring to expand the circumferential confinement surface. As an alternative, which is preferred, the restriction member comprises two elongated helical springs forming part of the circumferential confinement surface and connected to the body of the restriction member. The adjustment means is adapted to rotate each spring in one direction to enlarge the coils of the spring to contract the circumferential confinement surface and to rotate the spring in the opposite direction to reduce the size of the coils of the spring to expand the circumferential confinement surface.

In accordance with a third adjustment principle, the restriction member comprises at least two separate elements, at

least one of which is pivoted so that it may turn in a plane in which the loop of the restriction member extends, and the adjustment means is adapted to turn the pivoted element to change the size of the restriction opening. Preferably, the restriction member comprises a plurality of separate pivoted elements disposed in series, each pivoted element being turnable in the plane, and the adjustment means is adapted to turn all of the pivoted elements to change the size of the restriction opening. For example, the pivoted elements may comprise lamellae arranged like the conventional adjustable aperture mechanism of a camera.

In accordance with a fourth adjustment principle, the adjustment means is adapted to fold at least two foldable frame elements of the restriction member towards each other. Preferably, the foldable frame elements comprise two substantially semi-circular frame elements which are hinged together so that the semi-circular elements are swingable relative to each other from a fully open state in which they form a circle to a fully folded state in which they form a semi-circle.

In accordance with a fifth adjustment principle, the adjustment means is adapted to turn the restriction member around a longitudinal extension thereof, the elongated restriction member being elastic and varying in thickness as seen in a cross-section therethrough. Suitably, the elongated restriction member comprises an elastic belt.

In all of the above-described embodiments of the invention the adjustment means is conveniently operated by any suitable motor, preferably an electric motor, which may be fixed directly to or be placed in association with the restriction member, or alternatively be located remote from the restriction member, advantageously in the abdomen or subcutaneously. In the latter alternative the motor is advantageously connected to the adjustment means by a flexible power transmission conduit to permit a suitable positioning of the motor in the abdomen of the patient. The motor may be manually activatable, for example by an implanted switch.

In some of the above described embodiments of the

invention, however, the adjustment means may conveniently be operable by a hydraulic operation means, which preferably is manually activatable. The hydraulic operation means may advantageously include hydraulic servo means to facilitate manual activation. As an alternative, the hydraulic means may be powered by an electric motor, which may be manually activatable or controlled by remote control means. The components of such a hydraulic operation means may be placed in association with the restriction member and/or be located at a suitable place in the abdomen or subcutaneously. More specifically, a reservoir may be provided containing a predetermined amount of fluid for supplying the hydraulic operation means with fluid. The reservoir defines a chamber for the predetermined amount of fluid and the hydraulic operation means is adapted to change the size of the chamber. The hydraulic operation means may comprise first and second wall portions of the reservoir, which are displaceable relative to each other to change the size of the chamber of the reservoir. The first and second wall portions of the reservoir may be designed to be displaceable relative to each other by manual manipulation thereof, preferably to permit manual pushing, pulling or rotation of any of the wall portions in one direction. Alternatively, the wall portions may be displaceable relative to each other by magnetic means (such as a permanent magnet and magnetic material reed switch, or other known or conventional magnetic devices), hydraulic means or electrical control means such as an electric motor. The magnetic means, hydraulic means, or electrical control means may all be activated by manual manipulation, preferably using a subcutaneously located manually manipulatable device. This control may be indirect, for example via a switch.

The hydraulic operation means may be adapted to operate the adjustment means with fluid from the reservoir in response to a predetermined first displacement of the first wall portion of the reservoir relative to the second wall portion of the reservoir, to increase the size of the restriction opening, and to operate the adjustment means with fluid from the reservoir in response to a predetermined second displacement of

the first wall portion of the reservoir relative to the second wall portion of the reservoir, to decrease the size of the restriction opening. In this embodiment, no pump is used, only the volume of the reservoir is varied. This is of great advantage compared to the solution described below when a pump is used to pump fluid between the reservoir and the adjustment means because there is no need for a non-return valve and it is still possible to have fluid going both to and from the reservoir.

As an alternative, the hydraulic operation means may comprise an activatable pump adapted to pump fluid between the reservoir and the adjustment means. The pump may pump fluid both to and away from the adjustment means, or hydraulic means controlling the adjustment device. A mechanical manual solution is proposed in which it is possible to pump in both directions just by pushing an activating member in one direction. Another alternative is a pump pumping in only one direction and an adjustable valve to change the direction of fluid to either increase or decrease the amount of fluid in the reservoir. This valve may be manipulated manually, mechanically, electrically, magnetically, or hydraulically. Any kind of motor could of course be used for all the different operations as well as wireless remote solutions. The pump may comprise a first activation member for activating the pump means to pump fluid from the reservoir to the adjustment means and a second activation member for activating the pump means to pump fluid from the adjustment means to the reservoir. The activation members may be operable by manual manipulation, preferably to permit manual pushing, pulling or rotating thereof in one direction. Suitably, at least one of the activation members is adapted to operate when subjected to an external pressure exceeding a predetermined magnitude.

Alternatively, at least one of the first and second activating members may be operable by magnetic means, hydraulic means or electrical control means such as an electric motor. The magnetic means, hydraulic means, or electrical control means may all be activated by manual manipulating means preferably located subcutaneously. This activation may be

indirect, for example via a switch.

Advantageously, especially when manual manipulation means are used, a servo means system could be used. With servo means less force is needed for controlling the adjustment device. Hydraulic means is preferably used with servo means. One example is a closed system that controls another closed system in which the hydraulic means of the adjustment means is incorporated. Minor changes in the amount of fluid in a reservoir of the first system could then lead to major changes in the amount of fluid in a reservoir in the second system. In consequence, the change of volume in the reservoir of the second system affects the hydraulic means of the adjustment means, which is incorporated in the second closed system. The great advantage of this servo system is that the larger volume system could be placed inside the abdomen where there is more space and still would be possible to use manual manipulation means of the smaller system subcutaneously. The servo reservoir could control the reservoir of the larger volume. The servo reservoir could be controlled directly or indirectly by a fluid supply means. The fluid supply means may be a small reservoir, which may be placed subcutaneously and may be activated by manual manipulation means controlling the servo reservoir.

Preferably, the servo means comprises hydraulic means and a servo reservoir and eventually a fluid supply reservoir. Both reservoirs define a chamber containing servo fluid, and the hydraulic means comprises first and second wall portions of the servo reservoir, which are displaceable relative to each other to change the size of the chamber of the servo reservoir. The hydralic means may control the adjustment means indirectly, *e.g.* via an increased amount of fluid in the servo reservoir, in response to a predetermined first displacement of the first wall portion of any of the reservoirs relative to the second wall portion of the reservoir to decrease the size of the restriction opening, and to control the adjustment means in response to a second displacement of the first wall portion of any reservoir relative to the second wall portion, to indirectly increase the size of the restriction opening. The wall portions of the reservoirs may be designed to be

displaceable relative to each other by manual manipulation thereof or be displaceable relative to each other by manually pushing, pulling or rotating any of the wall portions of the reservoir in one direction. Alternatively, the wall portions of the servo reservoir may be displaceable relative to each other by magnetic means, hydraulic means or electric control means including an electric motor.

The magnetic means, hydraulic means, or electrical control means may all be activated by manually manipulated means preferably located subcutaneously. This control may be indirect for example via a switch.

Even in the broadest embodiment of the invention the adjustment means may comprise a servo means. The servo means may comprise a hydraulic operation means, an electrical control means, a magnetic means, mechanical means or a manual manipulation means. The hydraulic operation means, electrical control means, mechanical means or magnetic means may be activated by manual manipulating means. Using a servo system will save the use of force when adjusting the adjusting means which may be of importance in many applications, for example when a battery cannot put out enough current although the total energy in the battery is more than enough to power the system.

All solutions may be controlled by a wireless remote control means for non-invasively controlling the adjustment means. The remote control means may advantageously be capable of obtaining information on the size of the restriction opening and to command the adjustment means to adjust the restriction member in response to obtained information.

The remote control means comprises means for wireless transfer of energy from outside the patient's body to energy consuming implantable components of the device. An implantable motor may suitably be provided for operating the adjustment means and said means for wireless transfer of energy may be adapted to directly power the motor with transferred energy. The energy transferred by said means for transfer of energy may comprise wave signals, an electric field or a magnetic field.

Preferably, the wireless remote control means comprises

separate signal transmitting means and implantable signal receiving means. For example, the signal transmitting and signal receiving means may be adapted to transmit and receive signals in the form of digital pulses, which may comprise a magnetic or electric field. Alternatively, which is preferred, the signal transmitting and signal receiving means may be adapted to transmit and receive signals, which may comprise electromagnetic waves, sound waves or carrier waves for remote control signals. The receiving means may comprise a control unit adapted to control the adjustment means in response to signals from the signal transmitting means.

The food intake restriction device may further comprise an implantable energizer unit for providing energy to energy consuming components of the device to be implanted in the patient, such as electronic circuits and/or a motor for operating the adjustment means. The control unit may be adapted to power such an implanted motor with energy provided by the energizer unit in response to signals received from the signal transmitting means. Any known or conventional signal transmitting or signal receiving device that is suitable for use with a human or mammal patient may be provided as the signal transmitting or signal receiving means. The signals may comprise electromagnetic waves, such as infrared light, visible light, laser light, micro waves, or sound waves, such as ultrasonic waves or infrasonic waves, or any other type of wave signals. The signals may also comprise electric or magnetic fields, or pulses. All of the above-mentioned signals may comprise digital signals.

The motor may be any type of motor, such as a pneumatic, hydraulic or electric motor and the energizer unit may be adapted to power the motor with pressurized gas or liquid, or electrical energy, depending on the type of motor. Where the motor is an electric motor, it may power pneumatic or hydraulic equipment.

The energizer unit may comprise a power supply and the control unit may be adapted to power the motor with energy from the power supply. Preferably, the power supply is an electric power supply, such as a battery, and the motor is an electric

motor. In this case, the battery also continuously powers the circuitry of the signal receiving means between the adjustment operations, in order to keep the signal receiving means prepared for receiving signals transmitted from the signal transmitting means.

Ihe energizer unit may be adapted to transfer energy from the signals, as they are transmitted to the signal receiving means, into electric energy for powering the implanted electronic components. For example, the energizer unit may be adapted to transfer the energy from the signals into direct or alternating current.

In case there is an implanted electric motor for operating the adjustment means the energizer unit may also power the motor with the transferred energy. Advantageously, the control unit is adapted to directly power the electric motor with electric energy, as the energizer unit transfers the signal energy into the electric energy. This embodiment is particularly simple and does not require any recurrent invasive measures for exchanging empty power supplies, such as batteries, that is required in the first embodiment described above.

For adjustment means of the type that requires more, but still relatively low, power for its operation, the energizer unit may comprise a rechargeable electric power supply for storing the electric energy obtained and the control unit be adapted to power the electric motor with energy from the rechargeable electric power supply in response to signals received from the signal transmitting means. In an initial charging step the rechargeable power supply can be charged over a relatively long time (*e.g.* a few seconds up to a half hour) without powering the electric motor. In a following operating step, when the power supply has been charged with sufficient energy, the control unit powers the electric motor with energy from the charged power supply to operate the adjustment means, so that a desired change of the patient's stoma opening is achieved. If the capacity of the power supply is insignificant to achieve the necessary adjustment in one single operating step, the above steps may conveniently be repeated until the

desired adjustment is achieved.

The electric power supply suitably comprises an inexpensive simple capacitor. In this case, the electric motor may be a stepping motor.

The signal transmitting means may be adapted to transmit electromagnetic signals and the energizer unit be adapted to draw radiant energy from the electromagnetic wave signals, as they are transmitted to the signal receiving means, and transfer the radiant energy into electric energy.

Alternatively, the energizer unit may comprise a battery, an electrically operable switch adapted to connect the battery to the signal receiving means in an "on" mode when the switch is powered and to keep the battery disconnected from the signal receiving means in a "standby" mode when the switch is unpowered, and a rechargeable electric power supply for powering the switch. The control unit may be adapted to power the electric motor with energy from the battery in response to signals received from the signal transmitting means, when the switch is in its "on" mode. Advantageously, the energizer unit may be adapted to transfer wave energy from the signals, as they are transmitted to the signal receiving means, into a current for charging the rechargeable electric power supply, which suitably is a capacitor. Energy from the power supply is then used to change the switch from "off" (standby mode) to "on". This embodiment is suited for adjustment means of the type that require relatively high power for their operation and has the advantage that the electronic circuitry of the signal receiving means does not have to be powered by the battery between adjustment operations. As a result, the life-time of the battery can be significantly prolonged.

As an example, the signal transmitting means may be adapted to transmit electromagnetic wave signals and the energizer unit be adapted to draw radiant energy from the electromagnetic wave signals, as they are transmitted to the signal receiving means, and to transfer the radiant energy into said current. The energizer unit suitably comprises a coil of the signal receiving means for inducing an alternating current as electromagnetic wave signals are transmitted through the

coil and a rectifier for rectifying the alternating current. The rectified current is used for charging the rechargeable power source.

Alternatively, the signal transmitting and receiving means may solely be used for control signals and further signal transmitting and receiving means be provided for transferring signal energy to implanted components. By such a double system of signal transmitting and receiving means the advantage is obtained that the two systems can be designed optimally for their respective purposes, namely to transmit control signals and to transfer energy from signals.

As should be realized by a skilled person, in many of the above-described embodiments of the invention the adjustment means may be operated by control means or manual manipulation means implanted under the skin of the patient, such as a pump, an electrical switch or a mechanical movement transferring means. In the manual embodiment it is not necessary to use a motor for operating the adjustment means.

In embodiments including hydraulic transmission means, an injection port connected to the hydraulic means may be provided for enabling, normally single, once-and-for-all, calibration of the amount of fluid in the hydraulic system.

The invention will now be described in more detail with reference to the accompanying drawings, in which:

Fig. 1 is a schematic sectional view of a preferred first embodiment of the food intake restriction device in accordance with the invention;

Figs. 2 and 3 are cross-sectional views taken along the lines II-II and III-III, respectively, of Fig. 1;

Figs. 4 and 5 schematically show two alternative designs of the embodiment of Fig.1;

Fig. 6 schematically illustrates a motor arrangement for the design according to Fig. 5;

Fig. 7 is a schematic sectional view of a second embodiment of the device in accordance with the invention;

Fig. 8 schematically illustrates a hydraulic transmision conduit for the embodiment of Fig. 7;

Fig. 9 is a schematic sectional view of a third

embodiment of the device in accordance with the invention;

Fig. 10 is a modification of the embodiment of Fig.9;

Fig. 11 is a schematic view of a fourth embodiment of the device in accordance with the invention;

Figs. 12 and 13 are enlarged details of the embodiment of Fig. 11;

Fig. 14 is a cross-section along the line XIV-XIV of Fig. 11;

Fig. 15 is a schematic view of a fifth embodiment of the device in accordance with the invention;

Fig. 16 is an enlarged detail of Fig. 15;

Fig. 17 is a cross-section along the line XVII-XVII of Fig. 15;

Figs. 18 to 21 are schematic sectional views of a sixth, seventh, eighth and ninth embodiments, respectively, of the device in accordance with the invention;

Figs. 22 and 23 illustrate a fully open and a reduced restriction opening, respectively, of the embodiment of Fig. 21;

Fig. 24 is a schematic view of a tenth embodiment of the device in accordance with the invention;

Fig. 25 is an enlarged detail of the embodiment of Fig. 24;

Figs. 26 and 27 illustrate a fully open and a reduced restriction opening, respectively, of the embodiment of Fig. 24;

Fig. 28 schematically illustrates a cushion arrangement for protecting the stomach or esophagus of the patient;

Fig. 29A-D is a block diagram of four different principal embodiments of the invention;

Fig. 30A-D are cross-sectional views of a pump mechanism according to Fig. 29C, which pumps fluid in opposite directions by mechanically pushing a wall portion in only one direction;

Fig. 31 is a cross-sectional view of a reservoir having a variable volume controlled by a remote control motor, in accordance with a particular embodiment of the principal embodiment shown in Fig. 29B or 30B;

Fig. 32 is a cross-sectional view of a a reservoir having

a variable volume adjustable by manual manipulation, in accordance with a particular embodiment of the principal embodiment shown in Fig. 29B or 29D;

Fig. 33A is a front view of a hydraulic, pneumatic or mechanical servo system in accordance with a particular embodiment of the principal embodiment shown in Fig. 29D;

Fig 33B is a cross-sectional view taken along line VB-VB of Fig 33A;

Fig. 34 is a block diagram illustrating remote control components of the device of the invention; and

Fig. 35 is a schematic view of a circuitry used for the system of the block diagram of Fig.34.

Referring to the drawing figures, like reference numerals designate identical or corresponding elements throughout the several figures.

Figs. 1-3 show a preferred embodiment of the food intake restriction device of the invention comprising a restriction member in the form of a circular resilient core 2 with two overlapping end portions 4,6. The core 2 defines a substantially circular restriction opening and is enclosed in an elastic soft hose 8 except at a releasable and lockable joint 10 of the core 2, which when released enables application of the core 2 with its hose 8 around the esophagus or the stomach of a patient. The materials of all of these elements are bio-compatible so that the patient's body will not reject them. A post-operation mechanical adjustment means 12 for mechanically adjusting the longitudinal extension of the core 2 to change the size of the restriction opening comprises a drive wheel 14 in frictional engagement with the overlapping end portions 4,6 of the core 2. The drive wheel 14 is journalled on a holder 16 placed in the hose 8 and provided with two counter pressure rollers 18,20 pressing the respective end portions 4, 6 of the core 2 against the drive wheel 14 to increase the frictional engagement therebetween. An electric motor 22 is connected to the drive wheel 14 via a long flexible drive shaft 24 and is moulded together with a remote controlled power supply unit 26 in a body 28 of silicone rubber. The length of the flexible drive shaft 34 is selected so that the

body 28 can be placed in a desired position in the patient's body, suitably in the abdomen.

If some time after the operation the patient needs an adjustment of the restriction opening of the core 2, the power supply unit 26 is controlled to power the electric motor 22 either to turn the drive wheel 14 in one direction to reduce the diameter of the core 2 or to turn the drive wheel 14 in the opposite direction to increase the diameter of the core 2.

Alternatively, a rack gear may be formed on one of the end portions 4,6 of the core 2 and the drive wheel 14 may be replaced by a drive gear wheel connected to the other end portion of the core 2 and in mesh with the rack gear.

Fig.4 shows an embodiment of the invention which is identical to the embodiment of Figs. 1-3, except that the motor 22 is encapsulated in a lateral protrusion 30 of the hose 8 so that it is fixed to the core 2 and has a short drive shaft 32 onto which the drive wheel 14 is mounted, the motor 22 being positioned relative to the circular core 2 such that the drive shaft 32 extends radially thereto.

Fig. 5 shows an embodiment of the invention which likewise is identical to the embodiment of Figs. 1-3, except that the motor 22 is encapsulated in the hose 8 so that it is fixed to the core 2 and has a short drive shaft 32, the motor 22 being positioned relative to the core 2 such that the drive shaft 32 extends substantially tangentially to the circular core 2. There is an angular gearing 34 connecting the drive shaft 32 to the drive wheel 14.

Fig. 6 shows a suitable arrangement for the motor 22 in the embodiment of Fig. 5, comprising a first clamping member 36 secured to one end portion of the core 2 and a second clamping member 38 secured to the other end portion 6 of the core 2. The motor 22 is secured to the first clamping member 36 and is operatively connected to a worm 40 via a gear transmission 42. The worm 40 is journalled at its opposite ends on holders 44 and 46, which are rigidly secured to the clamping member 36 and the motor 22, respectively. The second clamping member 38 has a pinion in mesh with the worm 40. When the motor 22 is powered the worm 40 rotates and will thereby pull the end

portion 6 of the core 2 in one or the opposite longitudinal direction, so that the diameter of the substantially circular core 2 is either increased or decreased.

Fig. 7 shows an embodiment of the invention in which a restriction member comprises an elongated core 48 and a helical spring 50. A spring contracting means in the form of a flexible pulling member 52, *i.e.* a string, wire or cable, is connected to the core 48 at one end thereof and extends through the helical spring 50. A hydralic motor in the form of a cylinder/piston unit 54 is adapted to pull the flexible pulling member 52 to contract the helical spring 50 against an arresting member 56, which is fixed relative to the core 48. A tube 58 hinged to the arresting member 56 extends between the cylinder/piston unit 54 and the arresting member 56, the flexible pulling member 52 running through the tube 58 and being connected to the piston of the cylinder/piston unit 54. Fig. 8 shows a similar embodiment in which a hydraulic transmission conduit 59 is provided between two piston-cylinder assemblies 54, for use as the hydraulic motor/device in Fig. 7.

Fig. 9 shows an embodiment of the invention in which the restriction member comprises two elongated helical springs 60 and 62 having free ends, and a body 64 to which the springs 60,62 are nonrotatably secured at their opposite ends. The body 64 comprises two separate parts secured to opposite end portions of the enclosing elastic hose 8 and is designed with a releasable and lockable joint between the separate parts. An adjustment means in the form of a drive shaft 66 has two opposite end portions connected to the helical springs 60,62, respectively, at their free ends. The coils of the springs 60,62 form left and right hand helices, respectively. A motor 68 is adapted to rotate the drive shaft 66 in one direction to enlarge the coils of the helical springs 60,62 to longitudinally contract the springs 60,62 and to rotate the drive shaft 66 in the opposite direction to reduce the size of the coils of the springs 60,62 to longitudinally extend the springs 60,62. Thus, the elongated helical springs 60,62 defines a restriction opening, the size of which is increased when the springs 60,62 are extended and decreased when the

springs 60,62 are contracted.

Fig. 10 shows an embodiment according to the invention which is identical to the embodiment of Fig.9, except that the adjustment means comprises a gearing having an input shaft 72 and two opposite aligned output shafts 74 and 76 connected to the helical springs 60 and 62, respectively, at their free ends. The input shaft 72 is connected to the output shafts 74,76 such that they rotate at opposite directions upon rotation of the input shaft 72. The coils of the springs 60, 62 form the same helices.

Figs. 11-14 show an embodiment of the device of the invention in which a hydraulic motor comprises two interconnected cylinders 78 and 80 and two pistons 82 and 84 in the respective cylinders 78,80. The cylinders 78,80 have a common fluid supply inlet member 86, which together with the cylinders 78,80 takes the shape of a Y-pipe. The restriction member comprises an elongated resilient arcuate core 88. The adjustment means comprises two bars 90 and 92 secured to opposite ends of the core 88 and connected to the pistons 82 and 84, respectively. The core 88 defines a restriction opening and is provided with a releasable and lockable joint 94 (Fig. 13) to permit application of the core 88 around the esophagus or stomach. The core 88 and the cylinders 90,92 are enclosed by a soft elastic hose 96 except at the joint 94 and the inlet member 86. The hose 96 has an outer tubular wall 98 and a central coaxial inner tubular wall 100, which is fixed to the outer wall 98 by spoke members 102 (Fig. 14). The core 88 is loosely fit in the inner tubular wall 100. By supplying fluid to or withdrawing fluid from the inlet 86 the pistons 82 and 84 will move towards or from each other, so that the restriction opening defined by the core 88 is changed by the longitudinal displacement of the bars 90,92.

Figs. 15-17 show an embodiment of the invention which is identical to the embodiment of Figs. 11-14, except that the adjustment means comprises an elongated voltage responsive element 104 secured to the opposite ends of the core 88, so that the core 88 and the element 104 form the restriction member. The element 104 is capable of bending inwardly into a

bow in response to a voltage applied across the element 104. The radius of curvature of said bow is adjustable by changing the level of the voltage applied to element 104.

Fig. 18 shows an embodiment of the device of the invention comprising a loop forming means in the form of a substantially rigid outer circular element 106 with a releasable and lockable joint 108 to enable application of the device around the esophagus or stomach. In this embodiment the restriction member comprises an elastic inner circular element 110 formed by the innermost wall portion of an elastic hose 112 extending along the outer element 106. The inner circular element 110 is disposed concentrically within the outer circular element 106. The adjustment means comprises a plurality of threads 114 secured to the elastic inner element 110 along the circumference thereof and running from the inner element 110 via guide members 116 attached to the outer element 106. By pulling all the threads 114 the inner elastic element 110 is pulled under expansion radially outwardly towards the outer element 106.

Fig. 19 shows an embodiment which is identical to the embodiment of Fig, 9, except that it comprises a loop forming means in the form of a substantially rigid outer circular element 118 supporting the helical springs 60,62, and a soft elastic inner wall 120 extending along the springs 60,62. When the motor 68 rotates the helical springs 60, 62 in a direction that enlarges the coils of the springs 60,62, the coils are forced by the rigid outer element 118 to expand radially inwardly thereby reducing the size of the restriction opening formed by the circumferential confinement surface of the restriction member (springs 60,62 and body 64).

Fig. 20 shows an embodiment of the invention in which a restriction member comprises a plurality of arcuate lamellae 122 arranged like the conventional adjustable aperture mechanism of a camera. The adjustment means, not shown, is conventional and is operated by a motor 124 to adjust the lamellae 122 to change the size of an restriction opening defined by the lamellae 122.

Figs. 21-23 show an embodiment of the invention in which

a restriction member comprises two semi-circular elements 126 and 128 which are hinged together such that the semi-circular elements 126,128 are swingable relative to each other between a fully open state in which they substantially form a circle, illustrated in Fig, 22 and an angular state, in which the size of the restriction opening defined by the semi-circular elements 126,128 is reduced, illustrated in Fig, 23. The adjustment means, not shown, is conventional and is operated by a motor 130 to swing the semi-circular elements 126,128 relative to each other.

Figs. 24-27 show an embodiment of the invention in which the restriction member comprises an elastic belt 130 forming a circle and having a substantially oval cross-section. The restriction member 130 is provided with a releasable and lockable joint 132. An elastic double walled hose 134 encloses the belt 130 except at the joint 132. The adjustment means, not shown, is conventional and is operated by a motor 136 to turn the belt 130 around the longitudinal extension thereof between a fully open state, in which the inner broader side of the belt 130 forms a substantially cylindrical surface, illustrated in Fig. 26, and a reduced open state, in which the inner broader side of the belt 130 forms a substantially conical surface, illustrated in Fig. 27.

Fig. 28 schematically illustrates a cushion arrangement for protecting the esophagus or stomach, comprising a plurality of cushions 138 disposed in series along a substantially circular holding member 140. This cushion arrangement may be utilized in any of the above described embodiments of the invention.

Figs. 29A-D provide a block diagram of four different hydraulic transmission configurations. Fig. 29A shows an adjustment means 202 of the restriction member, a separate reservoir 204, a one way pump 206 and an alternate valve 208. Fig. 29B shows the adjustment means 202 and an adjustable reservoir 210. Fig. 29C shows the adjustment means 202, a two way pump 212 and the reservoir 204. Fig. 30D shows a servo system with a first closed system controlling a second system. The servo system comprises the adjustable reservoir 210 and a

passive adjustable reservoir 214. Any of the reservoirs can be the active reservoir, either the servo reservoir 210 or the fluid supply reservoir 214. The reservoir 214 controls a larger adjustable reservoir 216 which is used for the operation of the adjustment means 202 for changing the restriction opening of the restriction member.

Figs. 30A-D are cross-sectional views of a pump mechanism adapted to pump fluid in both directions only by mechanically pushing a separate sealing wall portion 218 in one direction. Fig 30A shows a piston 220 pushed forwards against a spring 222 towards the wall portion 218 and located in a pump housing 224 conducting fluid from a right upper fluid passage 226 of the housing 224 to a left fluid passage 228 of the housing 224. A main valve 230 is open and a nonreturn valve 232 is closed. Fig. 30B illustrates the first pump movement in which the piston 220 has moved forwards and reaches the wall portion 218. Fig. 30C illustrates how the piston 220 moves backwards by the action of the spring 222. The main valve 230 is now closed and the nonreturn valve 232 is open for fluid from the right upper passage 226. Fig. 30D illustrates how the piston 220 is moved further downwards from its position according to Fig. 30B while pushing the wall portion 218 downwards against a second spring 234 that is stronger than spring 222, so that fluid escapes from a right lower fluid passage 236. When moving the piston 220 backwards from the position of Fig. 30D, fluid enters the left fluid passage 228 and a valve 238 in the lower right fluid passage 236 closes.

Fig 31 is a cross-sectional view of a reservoir 240 defining a chamber 242, the size of which is variable and is controlled by a remote controlled motor 244, in accordance with Fig. 29B or 29D. The reservoir 240 and the motor 244 are placed in a housing 246. The chamber 242 is varied by moving a large wall 248. The wall 248 is secured to a nut 250, which is threaded on a rotatable spindle 252. The spindle 252 is rotated by the motor 244 via an angular gearing, which comprises two conical gear wheels 254 and 256 in mesh with each other. The motor 244 is powered by a battery 258 placed in the housing 246. A signal receiving means 260 for controlling the

motor 244 is also placed in the housing 246. Alternatively, the battery 258 and the signal receiving means 260 may be mounted in a separate place. The signal receiving means may comprise any known or conventional device which is capable of receiving a control signal and then operating the motor 244.

Fig. 32 is a cross-sectional view of a reservoir 262 defining a chamber 264, the size of which is variable and is controlled by manual manipulation. A gable wall portion 266 of an open ended inner cylindrical housing 68 is adapted to be pushed downwards to fit in a desired locking groove 270 of a plurality of locking grooves 270 on the mantle wall of the cylindrical housing 268, to reduce the size of the chamber 64. The inner cylindrical housing 268 is suspended by springs 272 and is telescopically applied on an outer cylindrical housing 274. When pushing the inner cylindrical housing 268 it moves downwards relative to the outer cylindrical housing 274 causing the gable wall portion 266 to release from the locking groove 270 and move upwards relative to the inner cylindrical housing 268. When the inner housing 268 is moved upwardly by the action of the springs 272 the size of the chamber 264 is increased.

Fig. 33A and 33B show a servo means comprising a main ring-shaped fluid reservoir 276 defining a chamber 278, the size of which is variable. Centrally positioned in the main ring-shaped reservoir 276 there is a servo fluid reservoir 280 defining a chamber 282, the size of which is variable. The chamber 282 of the servo reservoir 280 is significantly smaller than the chamber 278 of the main reservoir 276. The two reservoirs 276 and 280 are situated between two opposite separate walls 284 and 286, and are secured thereto. When changing the amount of fluid in the servo reservoir 280, the two opposite walls 284,286 are moved towards or away from each other, whereby the size of the chamber 278 of the main reservoir 276 is changed.

Fig. 34 shows the basic parts of a remote control system of the implantable device of the invention including a motor, for instance the electric motor 22. In this case, the remote control system is based on the transmission of electromagnetic wave signals, often of high frequencies in the order of 100 kHz

- 1 gHz, through the skin 330 of the patient. In Fig. 34, all parts placed to the left of the skin 330 are located outside the patient's body and all parts placed to the right of the skin 330 are implanted in the patient's body.

An external signal transmitting antenna 332 is to be positioned close to a signal receiving antenna 334 implanted in the patient's body close to the skin 330. As an alternative, the receiving antenna 334 may be placed for example inside the abdomen of the patient. The receiving antenna 334 comprises a coil, approximately 1-100 mm, preferably 25 mm in diameter, wound with a very thin wire and tuned with a capacitor to a specific high frequency. A small coil is chosen if it is to be implanted under the skin of the patient and a large coil is chosen if it is to be implanted in the abdomen of the patient. The transmitting antenna 332 comprises a coil having about the same size as the coil of the receiving antenna 334 but wound with a thick wire that can handle the larger currents that is necessary. The coil of the transmitting antenna 332 is tuned to the same specific high frequency as the coil of the receiving antenna 334.

An external control unit 336 comprises a microprocessor, a high frequency electromagnetic signal generator and a power amplifier. The microprocessor of the control unit 336 is adapted to switch on/off the generator and to modulate signals generated by the generator to send digital information via the power amplifier and the antennas 332,334 to an implanted control unit 338. To avoid that accidental random high frequency fields trigger control commands, digital signal codes are used. A keypad placed on the external control unit 336 is connected to the microprocessor thereof. The keypad is used to order the microprocessor to send digital signals to either increase or decrease the size of the restriction opening defined by the loop of the restriction member (*e.g.* as described above). The microprocessor starts a command by applying a high frequency signal on the antenna 332. After a short time, when the signal has energized the implanted parts of the control system, commands are sent to increase or decrease the size of the restriction opening of the restriction

member in predefined steps. The commands are sent as digital packets in the form illustrated below.

Start pattern, 8 bits	Command, 8 bits	Count, 8 bits	Checksum, 8 bits

The commands are sent continuously during a rather long time period (*e.g.* 30 seconds or more). When a new increase or decrease step is desired the Count byte is increased by one to allow the implanted control unit 338 to decode and understand that another step is demanded by the external control unit 336. If any part of the digital packet is erroneous, its content is simply ignored.

Through a line 340, an implanted energizer unit 326 draws energy from the high frequency electromagnetic wave signals received by the receiving antenna 334. The energizer unit 326 stores the energy in a power supply, such as a large capacitor, powers the control unit 338 and powers the electric motor 22 via a line 342.

The control unit 338 comprises a demodulator and a microprocessor. The demodulator demodulates digital signals sent from the external control unit 336. The microprocessor of the control unit 338 receives the digital packet, decodes it and, provided that the power supply of the energizer unit 326 has sufficient energy stored, sends a signal via a signal line 344 to the motor 22 to either increase or decrease the size of the restriction opening of the restriction member depending on the received command code.

Alternatively, the energy stored in the power supply of the energizer unit may only be used for powering a switch, and the energy for powering the motor 22 may be obtained from another implanted power source of relatively high capacity, for example a battery. In this case the switch is adapted to connect the battery to the control unit 338 in an "on" mode when said switch is powered by said power supply and to keep said battery disconnected from the control unit in a "standby" mode when the switch is unpowered.

With reference to Fig. 35, the remote control system

schematically described above will now be described in accordance with a more detailed embodiment. The external control unit 336 comprises a microprocessor 346, a signal generator 348 and a power amplifier 350 connected thereto. The microprocessor 346 is adapted to switch the signal generator 348 on/off and to modulate signals generated by the signal generator 348 with digital commands that are sent to implanted components of the device of the invention. The power amplifier 350 amplifies the signals and sends them to the external signal transmitting antenna 332. The antenna 332 is connected in parallel with a capacitor 352 to form a resonant circuit tuned to the frequency generated by the signal generator 348.

The implanted signal receiving antenna coil 334 forms together with a capacitor 354 a resonant circuit that is tuned to the same frequency as the transmitting antenna 332. The signal receiving antenna coil 334 induces a current from the received high frequency electromagnetic waves and a rectifying diode 360 rectifies the induced current, which charges a storage capacitor 358. A coil 356 connected between the antenna coil 334 and the diode 360 prevents the capacitor 358 and the diode 360 from loading the circuit of the signal receiving antenna 334 at higher frequencies. Thus, the coil 356 makes it possible to charge the capacitor 358 and to transmit digital information using amplitude modulation.

A capacitor 362 and a resistor 364 connected in parallel and a diode 366 forms a detector used to detect amplitude modulated digital information. A filter circuit is formed by a resistor 368 connected in series with a resistor 370 connected in series with a capacitor 372 connected in series with the resistor 368 via ground, and a capacitor 374, one terminal of which is connected between the resistors 368,370 and the other terminal of which is connected between the diode 366 and the circuit formed by the capacitor 362 and resistor 364. The filter circuit is used to filter out undesired low and high frequencies. The detected and filtered signals are fed to an implanted microprocessor 376 that decodes the digital information and controls the motor 22 via an H-bridge 378 comprising transistors 380,382,384 and 386. The motor 22 can be

driven in two opposite directions by the H-bridge 378.

The microprocessor 376 also monitors the amount of stored energy in the storage capacitor 358. Before sending signals to activate the motor 22, the microprocessor 376 checks whether the energy stored in the storage capacitor 358 is enough. If the stored energy is not enough to perform the requested operation, the microprocessor 376 waits for the received signals to charge the storage capacitor 358 before activating the motor 22.

There are a number of other conceivable alternative embodiments of the invention that give the same result as the above-described embodiments. For example, the microprocessor of the external and implanted, respectively, control unit may be replaced by discrete components. The power amplifier of the external control unit may be omitted if the signals generated by the signal generator are strong enough. Therefore the invention is to be accorded the broadest interpretation of the appended claims to encompass all equivalent structures and assemblies.

One further advantage with this invention is that there may be a night button on the remote control setting the adjustment means in a position with a larger stoma diameter during the night, thus avoiding vomiting or nausa.

CLAIMS

1. A food intake restriction device for forming a stoma opening in the stomach or esophagus of a patient, the device comprising an elongated restriction member (2;48;60, 62;88;110;122;126,128;130), forming means (10;94;106; 108;118;132) for forming the elongated restriction member into at least a substantially closed loop around the stomach or esophagus, said loop defining a restriction opening (3), and an adjustment means (12;52;66;90,92;104;110) for adjusting the restriction member in said loop to change the size of said restriction opening, **characterised** in that the adjustment means (12;52;66;90,92;104;110) is designed to mechanically adjust the restriction member in a non-invasive manner to allow post-operation non-invasive adjustments of the restriction member.

2. The device according to claim 1, wherein the adjustment means (12;52;66;90,92) is adapted to adjust the longitudinal extension of the elongated restriction member (2;48;60,62;88) in said loop.

3. The device according to claim 2, wherein the restriction member (2;48) comprises a main portion and two elongated end portions (4,6), and the adjustment means (12;52;66;90,92) is adapted to establish longitudinal relative displacement between the end portions of the restriction member, such that the size of said restriction opening (3) is adjusted.

4. The device according to claim 3, wherein the adjustment means (12;52;66;90,92) comprises a movement transferring member (14;40;78,90;80,92) in engagement with at least one of the end portions (4,6) of the restriction member and operable to displace said one end portion relative to the other end portion of the restriction member.

5. The device according to claim 4, further comprising a motor (22), which is fixed relative to the main portion of the

restriction member (2) and has a rotating drive shaft (32) operatively connected to the movement transferring member (14).

6. The device according to claim 5, wherein the motor is positioned relative to the elongated restriction member such that the drive shaft extends in parallel with a chord in said loop of the restriction member.

7. The device according to claim 2, wherein the elongated restriction member (48,50) is longitudinally resilient and the adjustment means comprises a contracting means (52) adapted to longitudinally contract the resilient restriction member.

8. The device according to claim 7, wherein the elongated restriction member comprises a substantially nonresilient main portion (48) and an end portion forming an elongated helical spring (50), which is contractable by the contracting means (52).

9. The device according to claim 8, wherein the contracting means comprises an elongated flexible pulling member (52) connected to the main portion (48) of the restriction member and extending through the helical spring (50) to contract the helical spring against an arresting member (56), which is fixed relative to the main portion of the restriction member.

10. The device according to claim 2, wherein the restriction member comprises an elongated helical spring (60) having a free end, and a body (64) to which said spring is nonrotatably secured at its opposite end, the adjustment means (66) being adapted to rotate the helical spring in one direction to enlarge the coils of the helical spring to longitudinally contract the elongated helical spring and to rotate the helical spring in the opposite direction to reduce the size of the coils of the helical spring to longitudinally extend the helical spring.

11. The device according to claim 10, wherein the restriction

member comprises a further elongated helical spring (62) having a free end and nonrotatably secured to the body (64) at its opposite end, and the adjustment means comprises a drive shaft (66) having two opposite end portions connected to the helical springs, respectively, at their free ends, the helical coils forming left and right hand helices, respectively.

12. The device according to claim 11, wherein the restriction member comprises a further elongated helical spring (62) having a free end and nonrotatably secured to the body (64) at its opposite end, and the adjustment means comprises a gearing (70) having an input shaft (78) and two opposite aligned output shafts (74,76) connected to the helical springs (60,62), respectively, at their free ends, the input shaft being connected to the output shafts such that the output shafts rotate in the opposite directions upon rotation of the input shaft, the helical coils forming the same helices.

13. The device according to claim 1, wherein the restriction member (88;110;122) forms a radially innermost circumferential confinement surface in said loop of the restriction member, and the adjustment means (104;112) is adapted to mechanically adjust the restriction member such that at least a portion of the confinement surface is substantially radially displaced in said loop.

14. The device according to claim 13, wherein the adjustment means comprises an elongated voltage responsive element (104) forming part of the confinement surface and capable of bending into a bow in response to a voltage applied across the element, the radius of curvature of said bow being adjustable by changing the level of the voltage.

15. The device according to claim 13, wherein the restriction member comprises an elastic annular element (110) forming the confinement surface, and the adjustment means (112) is adapted to change the diameter of the elastic annular element.

16. The device according to claim 13, wherein the forming means comprises a substantially rigid outer annular element (118), and the restriction member comprises an elongated helical spring (60) extending internally along the outer annular element and contacting the latter, the helical spring forming part of the circumferential confinement surface and having a free end, and a body to which the helical spring is nonrotatably secured at its opposite end, the adjustment means being adapted to rotate the helical spring in one direction to enlarge the coils of the helical spring to contract the circumferential confinement surface and to rotate the helical spring in the opposite direction to reduce the size of the coils of the helical spring to expand the circumferential confinement surface.

17. The device according to claim 13, wherein the forming means comprises a substantially rigid outer annular element (118), and the restriction member comprises a first (60) and a second (62) elongated helical spring extending internally along the outer annular element and contacting the latter, the helical springs forming part of the circumferential confinement surface, the first and the second spring, respectively, having a free end, and a body to which the first and the second spring, respectively, is nonrotatably secured at its opposite end, the adjustment means being adapted to rotate the first and the second spring, respectively, in one direction to enlarge the coils of the spring to contract the circumferential confinement surface and to rotate the first and the second spring, respectively, in the opposite direction to reduce the size of the coils of the spring to expand the circumferential confinement surface.

18. The device according to claim 1, wherein the restriction member comprises at least two separate elements, at least one of which is pivoted such that it is turnable in a plane in which said loop of the restriction member extends, and the adjustment means is adapted to turn said pivoted element to change the size of said restriction opening.

19. The device according to claim 1, wherein the restriction member comprises at least two frame elements (126 and 128), which are foldable towards each other by the adjustment means.

20. The device according to claim 19, wherein the foldable frame elements comprise two substantially semi-circular frame elements (126 and 128), which are hinged together such that the semi-circular elements are swingable relative to each other from a fully open state in which they substantially form a circle to a fully folded state in which they form a semi-circle.

21. The device according to claim 1, wherein the elongated restriction member (130) is elastic and varies in thickness as seen in a cross-section therethrough, and the adjustment means is adapted to turn the restriction member around the longitudinal extension thereof.

22. The device according to claim 1, further comprising a motor (22;68;124;130;136) operatively connected to the adjustment means (12;52;66;90,92;104;110).

23. The device according to claim 22, wherein the motor (22;68;124;130;136) is fixed to the restriction member.

24. The device according to claim 23, wherein the motor (22) is remote from the the restriction member (2) and is connected to the adjustment means (14) by a power transmission conduit (24).

25. The device according to claim 1, further comprising hydraulic means (54) for operating the adjustment means (52).

26. The device according to claim 25, further comprising a reservoir (204;210;216) containing a predetermined amount of fluid for supplying the hydraulic means with fluid.

27. The device according to claim 26, wherein the reservoir

(210) defines a chamber for the predetermined amount of fluid and the hydraulic means (202) is adapted to change the size of the chamber.

28. The device according to claim 26, wherein the hydraulic means comprises an activatable pump (212) adapted to pump fluid between the reservoir (204) and the adjustment means (202).

29. The device according to claim 26, wherein the hydraulic means comprises a servo means (210,214;276-286).

30. The device according to claim 29, wherein the hydraulic means comprises first and second wall portions of the reservoir (204), and the servo means is adapted to provide relative displacement between the first and second wall portions of the reservoir.

31. The device according to claim 1, further comprising a wireless remote control means (22,326,332-344) for non-invasively controlling the adjustment means.

32. The device according to claim 31, wherein the remote control means (22,326,332-344) comprises a separate signal transmitting means (332,336) and an implantable signal receiving means (334,338).

33. The device according to claim 32, wherein the signal receiving means (334,338) comprises a control unit (338) adapted to control the adjustment means (12;52;66;90,92;104;110) in response to signals received from the signal transmitting means.

34. The device according to claim 33, further comprising an implantable energizer unit (336) for providing energy to energy consuming components of the device to be implanted in the patient.

35. The device according to claim 34, further comprising an

implantable motor (22) for operating the adjustment means (12;52;66;90,92;104;110).

36. The device according to claim 35, wherein the control unit (338) is adapted to power the motor (22) with energy provided by the energizer unit (336) in response to signals received from the signal transmitting means (332,336).

37. The device according to claim 33, wherein the motor (22) is an electric motor.

38. The device according to claim 34, wherein the energizer unit (326) is adapted to transfer energy from the signals, as they are transmitted to the signal receiving means (334,338), into electric energy.

39. The device according to claim 38, further comprising an implantable electric motor (22) for operating the adjustment means (12;52;66;90,92;104;110), the energizer unit (326) comprising a rechargeable electric power supply (58) for storing the electric energy and the control unit (338) being adapted to power the electric motor (22) with energy from the rechargeable electric power supply in response to signals received from the signal transmitting means (332,336).

40. The device according to claim 34, wherein the energizer unit (326) comprises a battery, an electrically operable switch adapted to connect the battery to the signal receiving means in (334,338) an "on" mode when the switch is powered and to keep the battery disconnected from the signal receiving means in a "standby" mode when the switch is unpowered, and a rechargeable electric power supply for powering the switch.

41. The device according to claim 40, wherein the control unit (338) is adapted to power the electric motor (22) with energy from the battery in response to signals received from the signal transmitting means (332,336), when the switch is in its "on" mode.

42. The device according to claim 2, wherein the forming means comprises a spring material forming the elongated restriction member into said loop, such that the restriction opening has a predetermined size, and the adjustment means is adapted to adjust the restriction member against the spring action of the spring material.

43. The device according to claim 42, wherein the spring material is integrated in the restriction member.

44. The device according to any of the preceding claims, wherein the forming means (10;94;106;108;118;132) is adapted to form the restriction member (2;48;60,62;88;110;122;126,128;130) into a loop having a predetermined size.

45. The device according to claim 31, wherein the remote control means (22,326,332-344) comprises means for wireless transfer of energy from outside the patient's body to energy consuming implantable components of the device.

46. The device according to claim 45, further comprising an implantable motor (22) for operating the adjustment means (12;52;66;90,92;104;110), said means for wireless transfer of energy being adapted to directly power the motor with transferred energy.

47. The device according to any of claims 45 and 46, wherein the energy transferred by said means for transfer of energy comprises wave signals.

48. The device according to any of claims 45 and 46, wherein the energy transferred by said means for transfer of energy comprises an electric field or a magnetic field.

49. The device according to any of claims 32 and 33, wherein the signal transmitting means (332,336) and signal receiving means (334,338) are adapted to transmit and receive signals in the form of digital pulses.

50. The device according to claim 49, wherein the digital pulses comprise a magnetic field or an electric field.

51. The device according to any of claims 32 and 33, wherein the signal transmitting means (332,336) and signal receiving means (334,338) are adapted to transmit and receive wave signals.

52. The device according to claim 51, wherein the wave signals comprise electromagnetic waves, sound waves or carrier waves for remote control signals.

53. The device according to any of claims 34 and 38, wherein the energizer unit (26) is adapted to transfer the energy from the signals into direct or alternating current.

54. The device according to claim 31, wherein the remote control means (22,326,332-344) is capable of obtaining information on the size of the restriction opening (3) and to command the adjustment means (12;52;66;90;104;110) to adjust the restriction member (2;48;60,62;88;110;122;126,128;130) in response to obtained information.

55. The device according to claim 1, wherein the adjustment means (12;52;66;90;104;110) is adapted to change the size of the restriction opening (3) such that the outer circumferential confinement surface of the restriction member (2;48;60,62;88;110;122;126,128;130) is changed.

56. The device according to claim 1, wherein the adjustment means (12;52;66;90;104;110) is adapted to change the size of the restriction opening (3) such that the outer circumferential confinement surface of the restriction member (2;48;60,62;88;110;122;126,128;130) is unchanged.

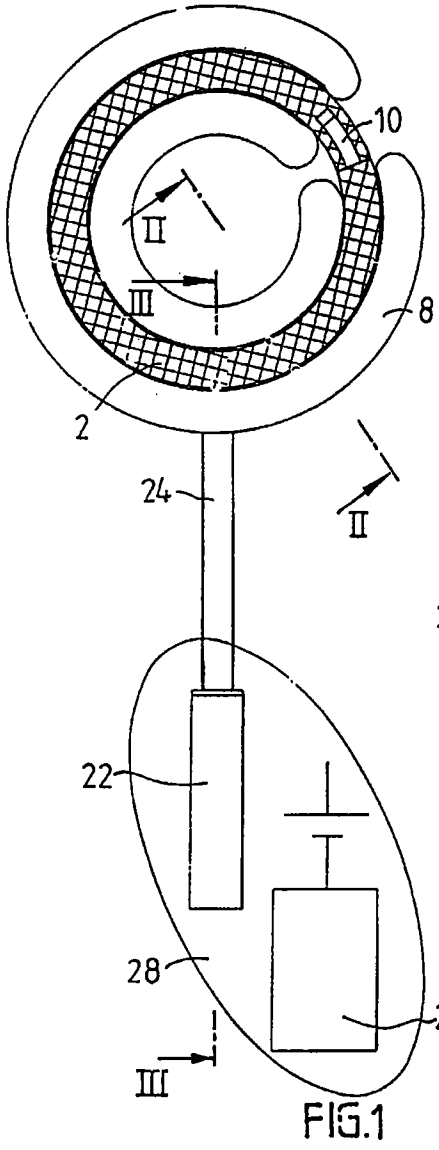


FIG.1

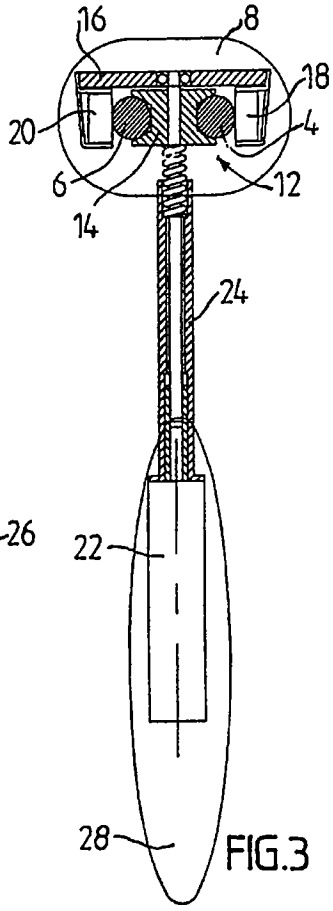


FIG.3

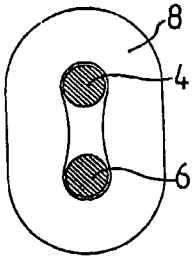


FIG.2

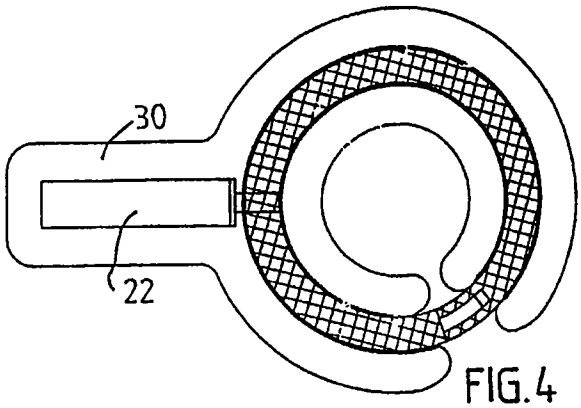


FIG.4

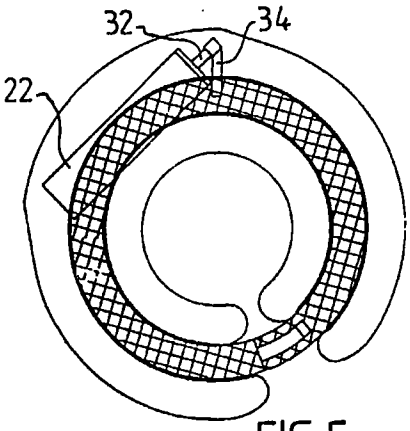


FIG.5

FIG.8

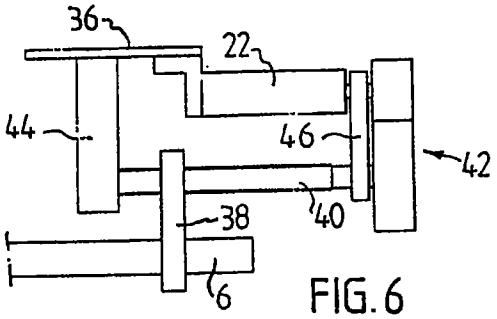


FIG.6

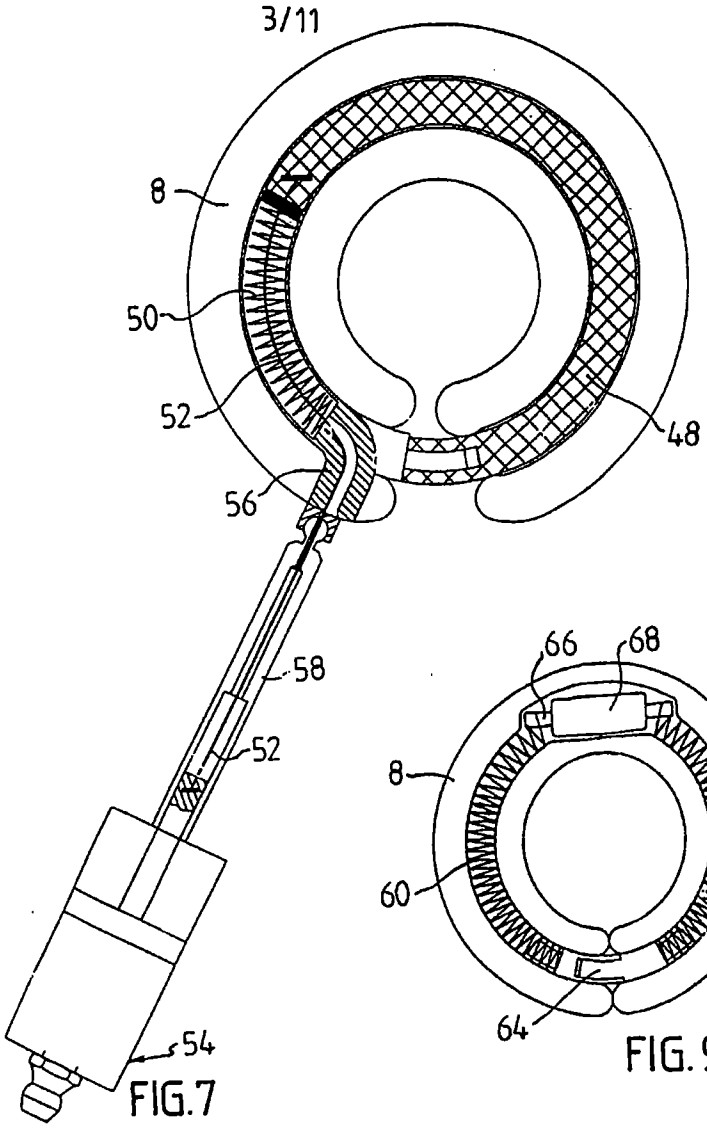


FIG.7

FIG.9

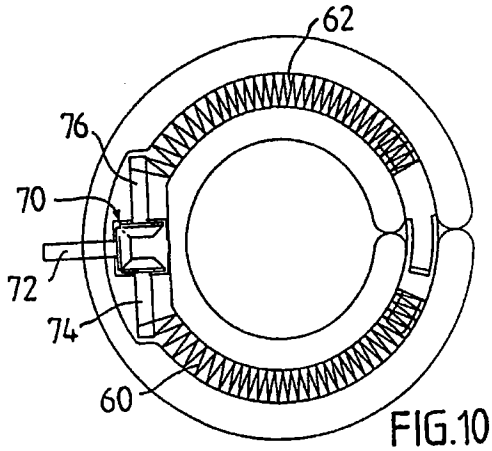


FIG.10

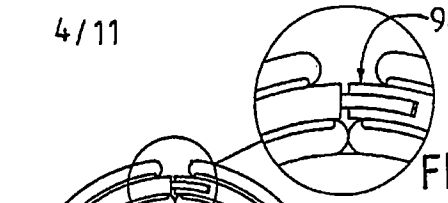


FIG.13

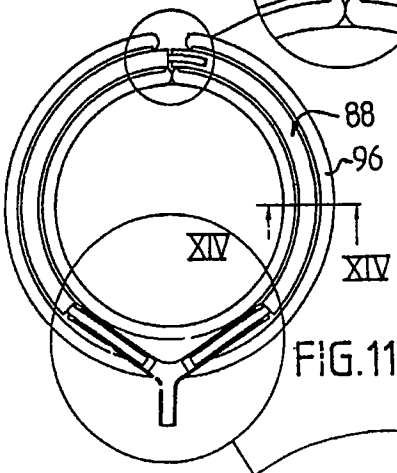


FIG.11

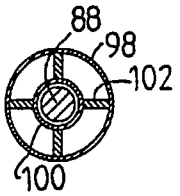


FIG.14

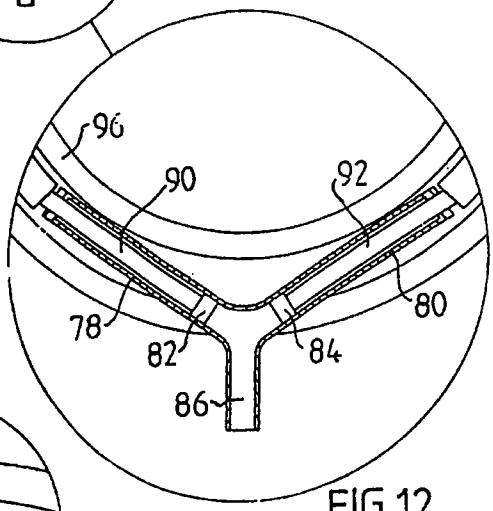


FIG.12

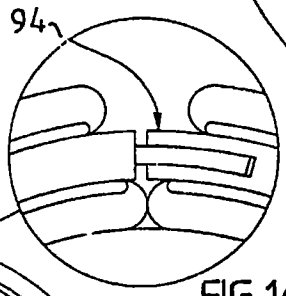


FIG.16

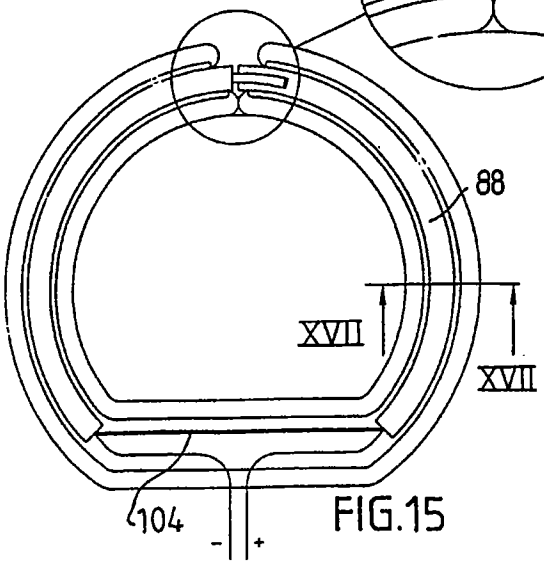


FIG.15

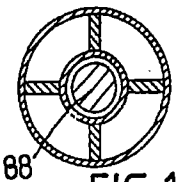


FIG.17

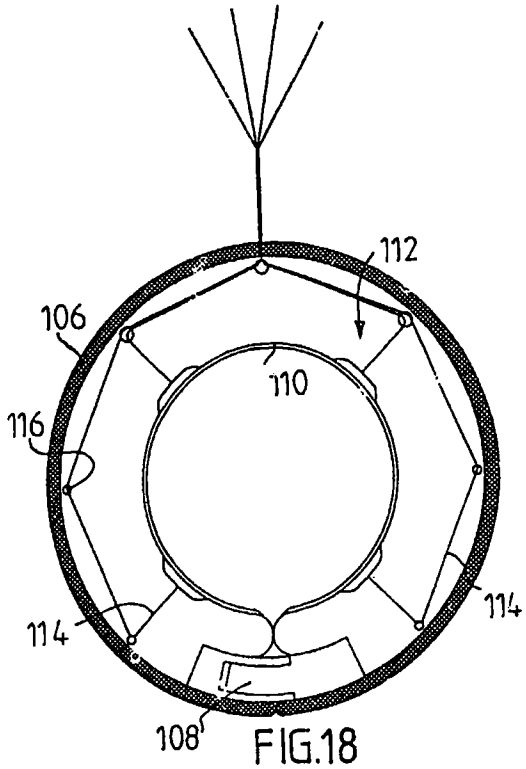


FIG.18

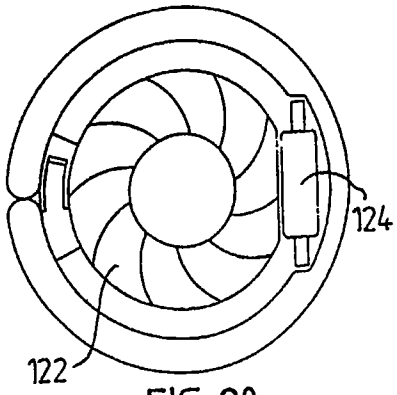


FIG. 20

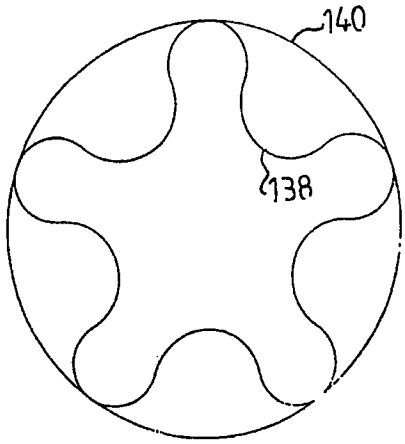


FIG. 28

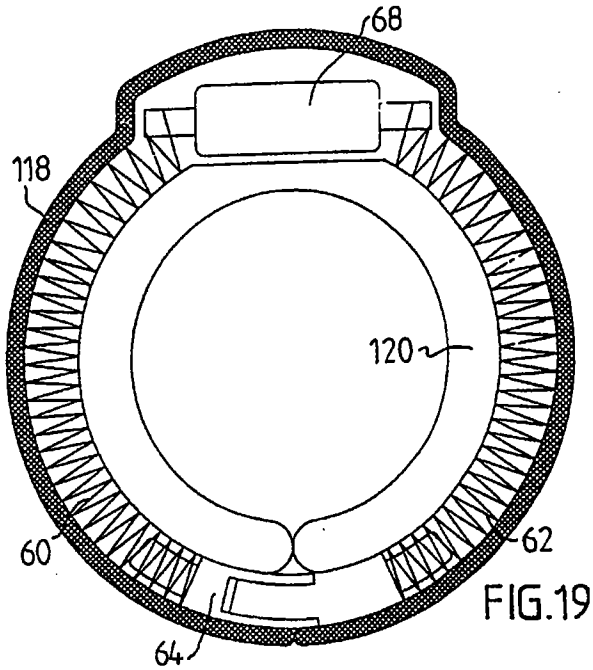


FIG.19

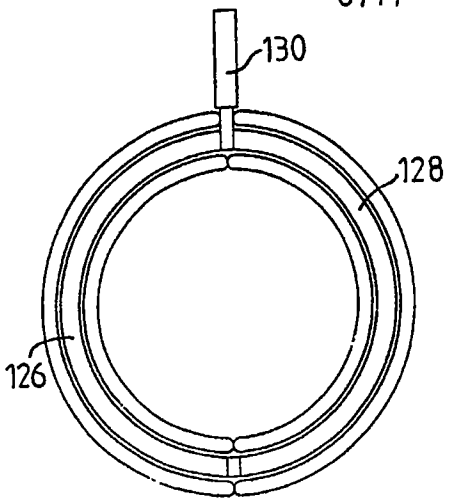


FIG. 21

FIG. 22

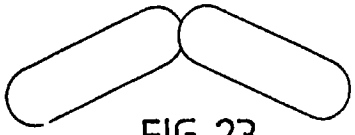
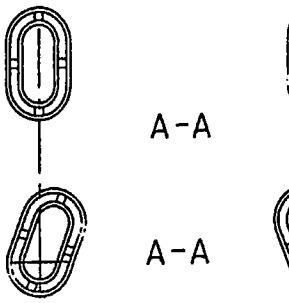


FIG. 23



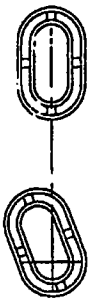


FIG. 26

FIG. 27

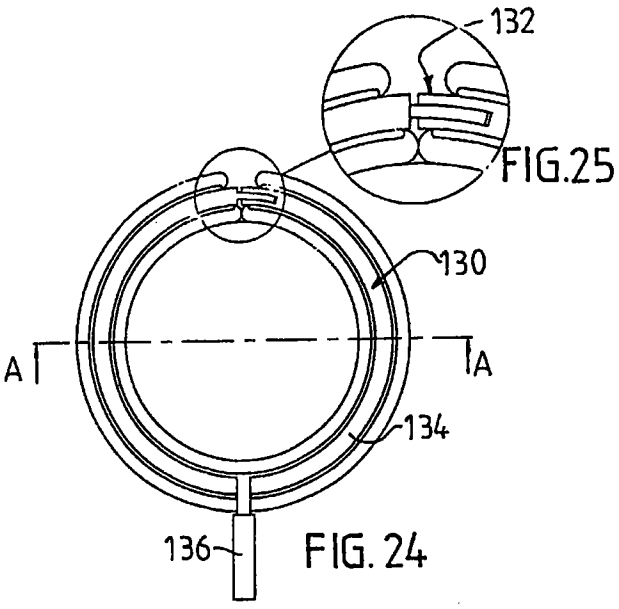


FIG. 25

FIG. 24

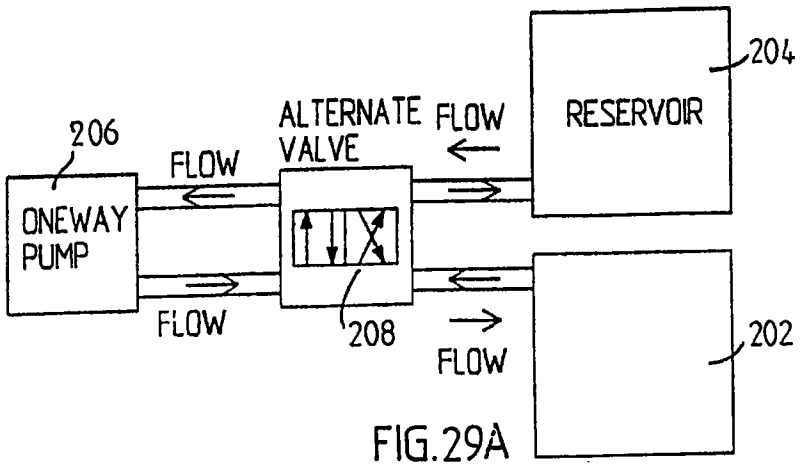


FIG.29A

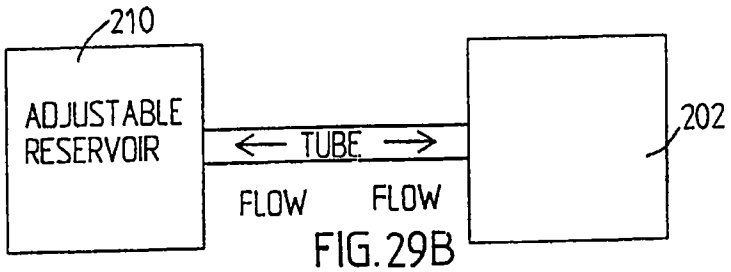


FIG.29B

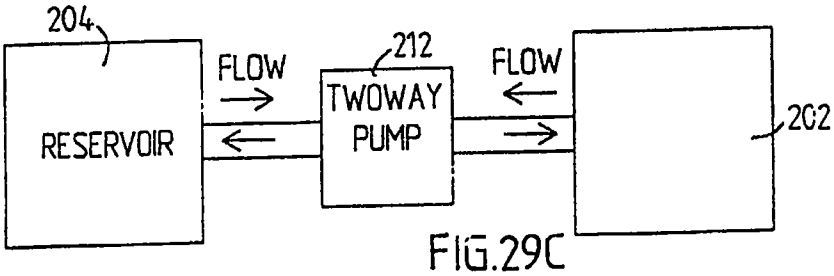


FIG.29C

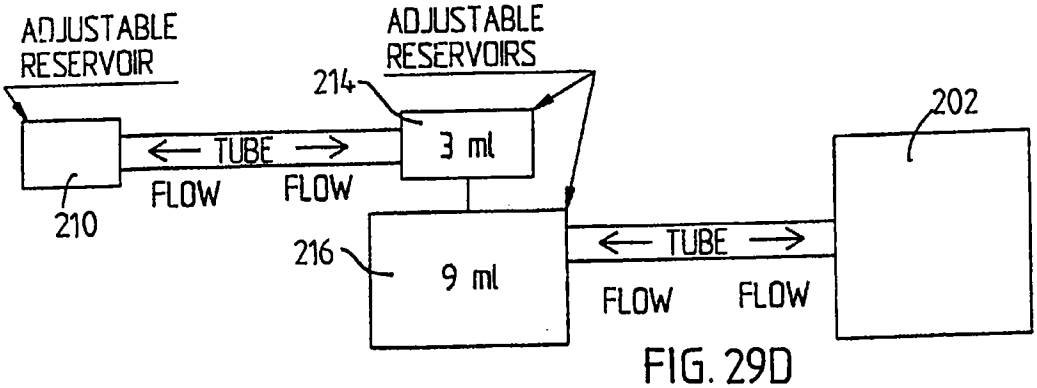


FIG. 29D

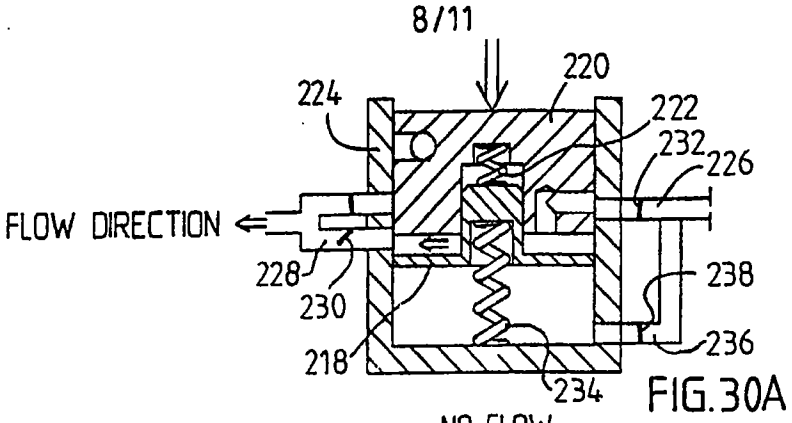


FIG.30A

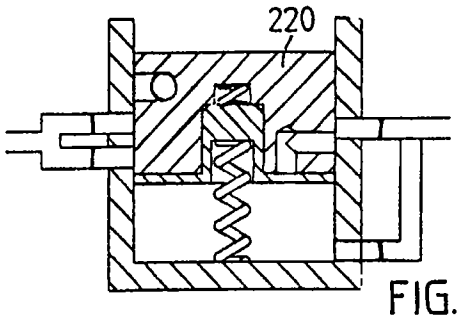


FIG.30B

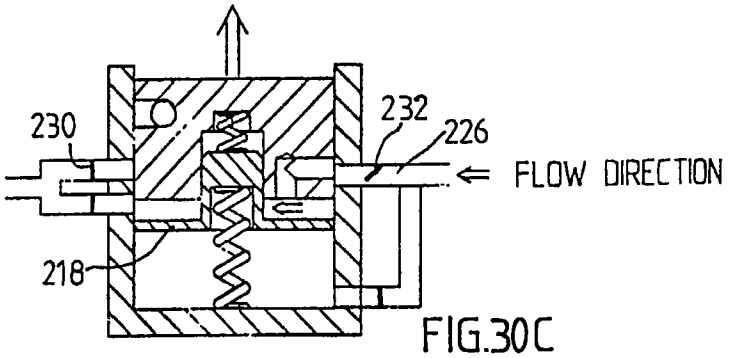


FIG.30C

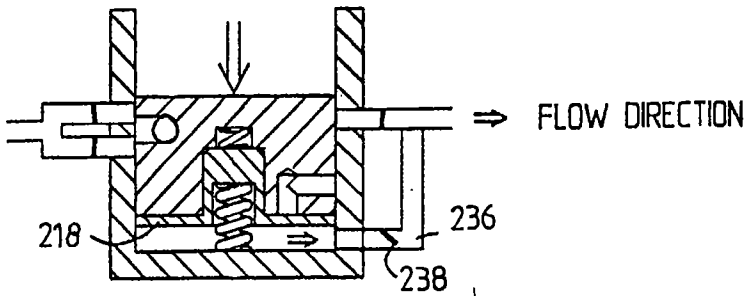


FIG.30D

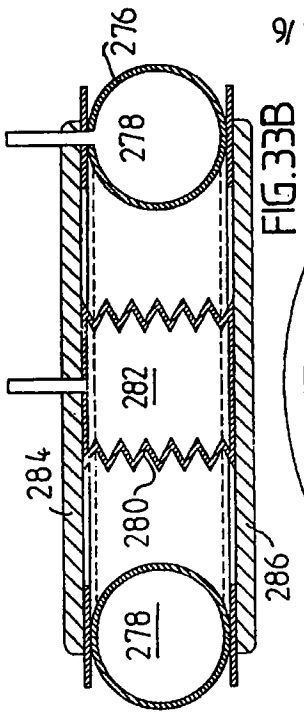


FIG.33B

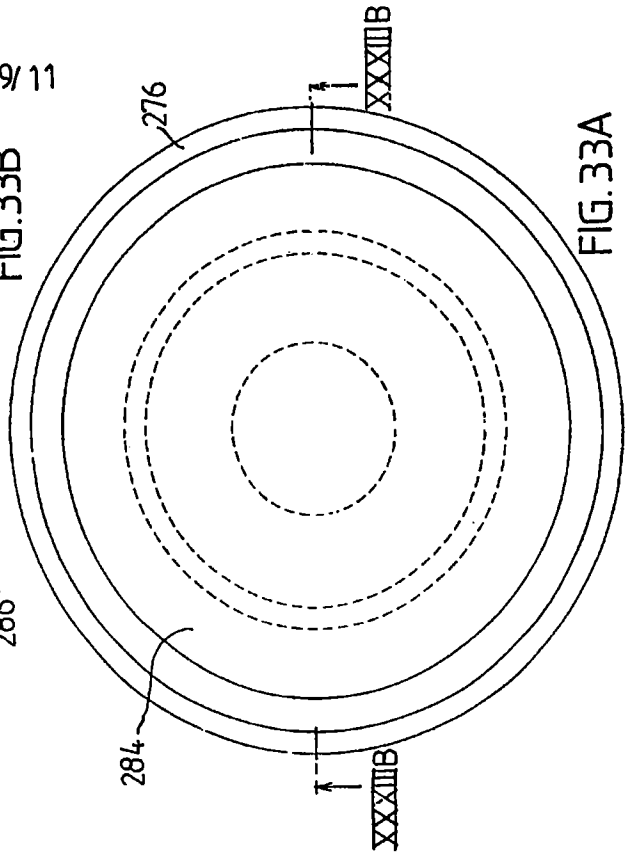


FIG.33A

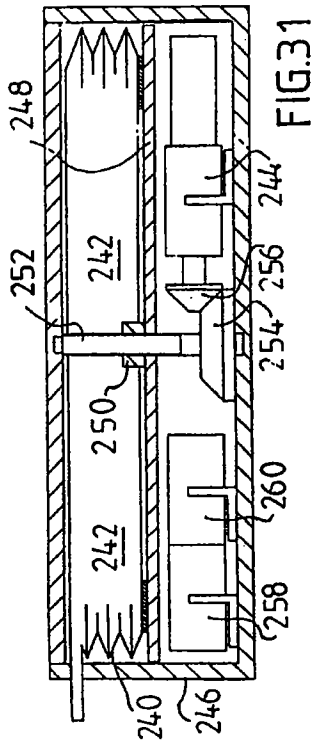


FIG.31

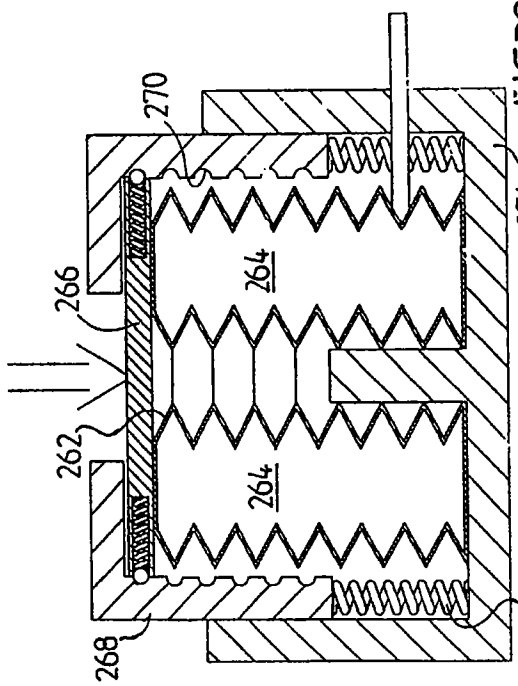


FIG32

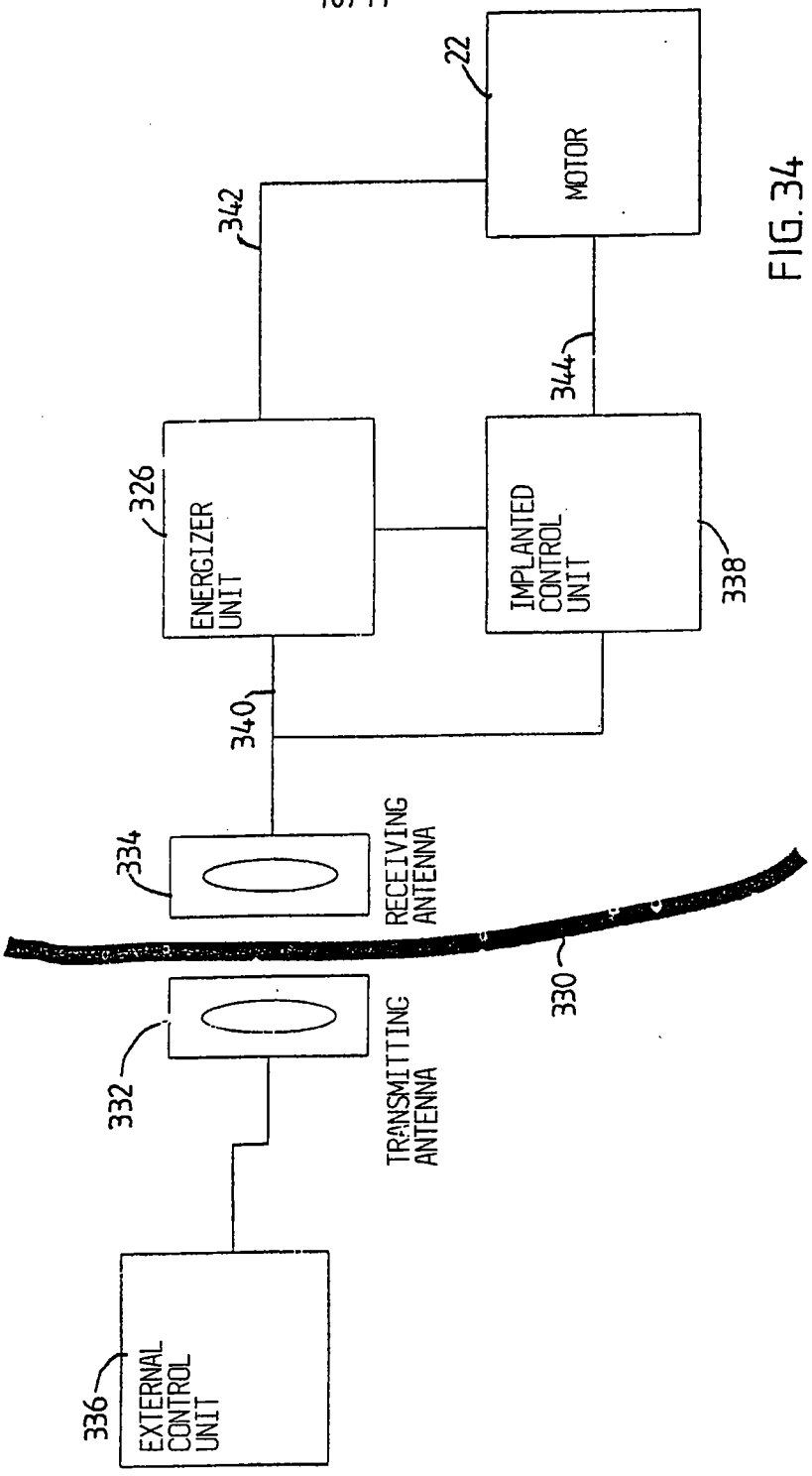
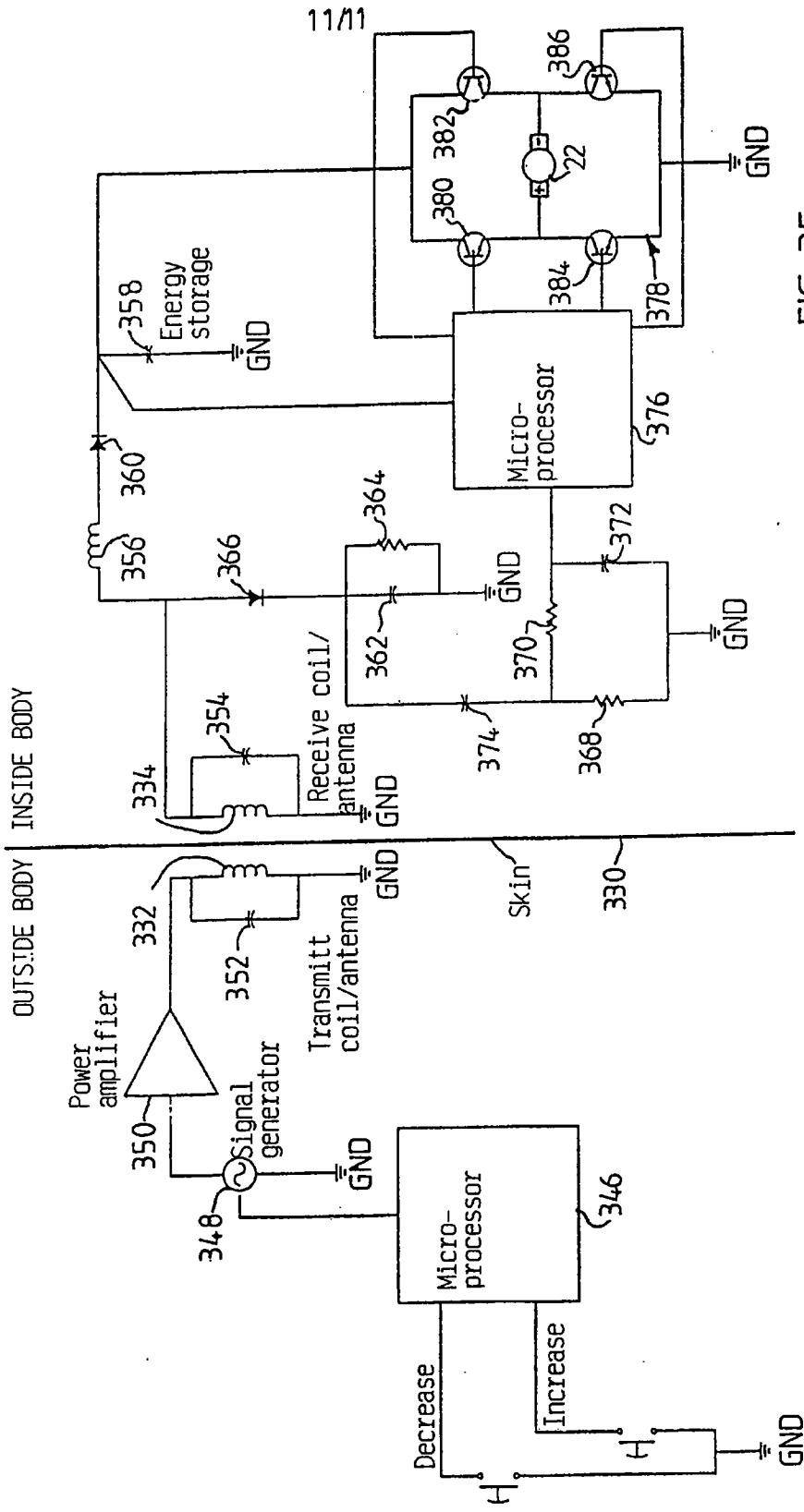

22
MOTOR
342
344
326
ENERGIZER UNIT
IMPLANTED CONTROL UNIT
338
340
334
RECEIVING ANTENNA
330
332
TRANSMITTING ANTENNA
336
EXTERNAL CONTROL UNIT

FIG. 34


OUTSIDE BODY
INSIDE BODY
Skin
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334
354
Receive coil/ antenna
GND
332
352
Transmitt coil/antenna
Power amplifier
350
Signal generator
348
Micro-processor
346
Decrease
Increase
358
Energy storage
360
356
366
364
362
374
370
372
368
Micro-processor
376
380
382
386
384
378
22

FIG. 35

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 99/01365

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 5/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	EP 0876808 A1 (KLASAMED S.A.), 11 November 1998 (11.11.98), abstract	1
A,P	--	2-56

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
18 November 1999	13.12.99
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Ingrid Falk / JA A Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

02/11/99

International application No.
PCT/SE 99/01365

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0876808 A1	11/11/98	US 5938669 A	17/08/99